10

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,988	01/25/2002	Paul A. Moore	PZ032P1C3	8271

22195 7590 07/13/2004

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,988	MOORE ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,13,17-20,22 and 24-117* is/are pending in the application.

4a) Of the above claim(s) *1,11,17-20,22,24,42,43,68,85,86 and 111* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,25-41,44-67,69-84,87-110 and 112-117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/904,615.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/04 and 3/14/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 11, 13, 17-20, 22 and 24-117 are pending.

2. Applicant's election with traverse of Group 162, claim 13 (now claims 13, 25-41, 44-67, 69-84, 87-110 and 112-117) drawn to an antibody against the polypeptide of SEQ ID NO:114 and clone ID HUVDJ43 (Gene No. 48) filed on 4/1/04, is acknowledged.

Applicant's traversal is on the grounds that no showing has been made by the examiner that the search and examination of the groups that relates to Gene No. 48 would entail a "serious burden". Further, Applicant submits that to search and examine the subject matter of all the groups together would not be serious burden on the Examiner because a search of the polypeptide claims would clearly provide useful information for the antibody claims. This is not found persuasive because the specific antibodies, polypeptides, and polynucleotide differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct. Further, the various methods recited in the instant application using the claimed antibodies differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct and searches of all groups would place an undue burden upon the examiner due to the distinct and divergent subject matter of each Group. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1, 11, 17-20, 22, 24, 42, 43, 68, 85, 86 and 111 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 13, 25-41, 44-67, 69-84, 87-110 and 112-117 are under examination as they read on an antibody against the polypeptide of SEQ ID NO:114 and clone ID HUVDJ43 (Gene No. 48).

5. The specification on page 1 should be amended to reflect the status of parent application No. 09/904,615.

6. The U.S. Patent 6,566,325 cited on the PTO FORM 892 is issued from the parental application serial No. 09/904,615.

7. Applicant's IDS, filed 3/14/02 and 4/1/04, is acknowledged. However, the references cited in the Search Report of EP 99 94 2469 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office Action.

Further, reference AA (filed on 4/1/04) has been considered but crossed out because while the Examiner acknowledges that provision of pending applications is appropriate. However, *if the inventorship is not the same* between the application in which the IDS was filed and the cited application, then the Office considers the application provided on the 1449 to be subject to 35 USC 122 requiring that the application be kept in confidence since it is not clear that all inventors of the cited application agree that the contents of that application should become publicly available.

In the instant case, although there are common inventors between the instant application and the application cited on the 1449/SB08A, the inventorship is not the same. Consequently, the citation has again been initialed as considered, but lined through to prevent printing of the cited application on the face of any patent that should issue from the instant application.

8. Claim 13 is objected to because it is dependent on a non-elected claim 11 and should be written as an independent claim. 1. Further, non-elected claim 11 recites sequence identifiers which are non-descriptive (SEQ ID NO:Y). Applicant is reminded that when a sequence is recited in the claims or disclosed in the specification, numerical sequence identifiers must be used (see 37 CFR 1.821(d)). Further, it is improper to refer to ATCC Deposit as Z. Applicant is requested to make the appropriate corrections in response to this action.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

10. Claims 13, 33-34, 36-37, 41, 44-50, 52-67, 69-84, 87-110, 112-117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The "fragment thereof" which is a human antibody in claims 33, 60, 76, 103 and 114 is ambiguous and indefinite because only intact antibody can be a human antibody and not an antibody fragment. It is suggested that said claims be amended to recite, for example "The antibody or fragment thereof of claim 28, wherein the antibody is a human antibody" (claim 33).

B. The "fragment thereof" which is a polyclonal antibody in claims 34 and 77 is ambiguous and indefinite because only antibody can be a polyclonal antibody and not an antibody fragment. It is suggested that the claims be amended to recite, for example "The antibody or fragment thereof of claim 28, wherein the antibody is a polyclonal antibody" (claim 34).

C. The "fragment thereof" which is a monoclonal antibody in claims 50, 93 and 113 is ambiguous and indefinite because only antibody can be a monoclonal antibody and not

an antibody fragment. It is suggested that the claims be amended to recite, for example "The antibody or fragment thereof of claim 44, wherein the antibody is a monoclonal antibody" (claim 50).

D. The "fragment thereof" in claims 41, 67, 84 and 110 is indefinite and ambiguous because hybridoma does not produce antibody fragment, hybridoma produce only a whole intact antibody. It is suggested that the claims be amended to recite, for example

   i. "The antibody or fragment thereof of claim 28, wherein the antibody is produced by a hybridoma" (claim 41) or

   ii. "A hybridoma that produces the antibody of claim 28" (claim 41).

E. The "fragment thereof" in claims 44-49 and 87-92 is indefinite and ambiguous because only antibody, not antibody fragment, can be obtained from animal that has been immunized with a protein. It is suggested that the claims be amended to recite, for example "An isolated antibody obtained from …" (claim 44).

F. Claims 36-37, 62-73, 79-80 and 105-106 have no antecedent basis in base claims 28, 55, 71 and 97, respectively, because claims 28, 55, 71 and 97 recite antibody or fragment thereof per se, whereas a labeled antibody or fragment thereof is recited in claims 36-37, 62-73, 79-80 and 105-106. It is suggested that claims 36-37, 62-73, 79-80 and 105-106 be changed to "A labeled antibody or fragment thereof, wherein the antibody or fragment thereof of claim (28, 55, 71 or 97) is labeled" and dependent claims thereof be changed to "The labeled antibody or fragment thereof of claim …".

G. Claims 13, 69, 87 and 95 are indefinite in the recitation "polypeptide encoded by the cDNA contained in ATCC Deposit Number 203081" because ATCC Deposit No. 203081 contain multiple different clones encoding multiple polypeptide and it unclear to which polypeptide the antibody is directed to.

H. Claim 13 (which depends from non-elected claim 11) is indefinite because the metes bounds of the "biological activity" recited in non-elected claim 11b are not established. Consequently, it is unclear what "biological activity" is contemplated.

I. Claim 112 is indefinite in the recitation "wherein said HUVDJ43 protein is encoded by a polynucleotide encoding amino acids 1-182 of SEQ ID NO: **2**". HUVDJ43 protein consists of amino acids 1-182 of SEQ ID NO: **114**. It is noted that SEQ ID NO: 2 has only 5 amino acids. It is unclear how a 5 amino acid sequence can be encoded by a polynucleotide encoding 1-182 amino acid residues.

J. Claim 52(d-e) is indefinite in the recitation "a protein consisting of a portion of SEQ ID NO: 2, wherein said portion comprises at least 30/50 contiguous amino acid residues of SEQ ID NO:**2**". SEQ ID NO:2 has only 5 amino acids, it is unclear how SEQ ID NO:**2** would comprise at least 30/50 contiguous amino acid residues.

5. 35 U.S.C. § 101 reads as follows:
"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

6. Claims 13, 25-41, 44-67, 69-84, 87-110 and 112-117 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility.

Applicants are directed to the Final Utility Guidelines, Federal Register, and Published Friday January 5, 2001.

The instant application has provided a description of an isolated polypeptide and an antibody against the polypeptide. The instant application does not disclose the biological role of the polypeptide or its significance. The instant specification asserts specific utilities for the claimed invention that the polynucleotides or polypeptides are useful as reagents for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of diseases and conditions which include, but not limited to, vascular and pulmonary disease and/or disorders, particularly atherosclerosis and microvascular disease (on pages 158, lines 13-17 in particular). The specification further discloses that polypeptides and polynucleotides corresponding to gene No. 48 (encodes SEQ ID NO: 114 (see Table 1, page 174, 5th row, in particular) play a role in the treatment/detection of lung lymphoma or sarcoma formation, pulmonary edema and embolism, bronchitis and cystic fibrosis. (page 159, lines 5-8, in particular). In addition, the specification asserts that expression in endothelial cells suggest a role in the treatment and/or detection of vascular disorders including vasculitis, cardiovascular disorders such as myocardial infarction, myocarditis, ischemia and stroke. The specification further discloses that the protein may be used to determine biological activity, to raise antibodies, as tissue markers, to isolate cognate ligands or receptors, to identify agents that modulate their interactions, in addition to its use as a nutritional supplement (see page 159 lines 10-14). Further, the specification asserts that antibodies which specifically binds polypeptide are useful in providing immunolgical probes for differential identification of the tissue(s) or cell type(s) (page 158, lines 17-18).

These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for SEQ ID NO: 114 or antibodies directed to SEQ ID NO: 114. The deduced 182-amino acid expressed primarily in endothelial cells however with undetermined biological function or use. After further research, specific and substantial utility might be found for the claimed isolated polypeptide or the antibody directed to the polypeptide. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The presence of a polynucleotide encoding polypeptide of SEQ ID NO: 114 in endothelial cells and the pulmonary system is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the polypeptide, which is the claimed antibody binds to, and the disease. Further, the US

2003/0004311 A1 publication teaches a polypeptide with 99.7% homology to claimed SEQ ID NO: 114, with one conservative amino acids difference. The `156 publication further teaches that the reference polypeptide can stimulate the release of TNF-α from human blood, modulate the uptake of glucose or free fatty acid by cells, stimulate or inhibit the proliferation or differentiation of cells or gene expression, stimulate the release of proteoglycans, stimuate the release of cytokine from peripheral blood mononuclear cells, inhibit the binding of A-peptide to factor VIIA, or detect the presence of tumor in a mammal (see the entire document). Thus, to employ the claimed antibody in the treatment and/or detection of vascular disorders including vasculitis, cardiovascular disorders such as myocardial infarction, myocarditis, ischemia and stroke would clearly be using it as the object of further research since other cells express the same polypeptide such as blood cells. Such non-specific detection can be done by any antibody or polynucleotide. Therefore, such a utility is not specific. Such a use has been determined by the courts to be a utility which, alone, does not support patentablility. Since the instant specification does not disclose a "real world" use for the antibodies directed to SEQ ID NO: 200, then the claimed invention as disclosed does not meet the requirement of 35 U.S.C. § 101 as being useful.

The instant situation is directly analogous to that which was addressed in *Brenner V. Manson*, 148 U.S. P. Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S. C. § 101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The instant claims are drawn to a polypeptide of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that antibodies directed to SEQ ID NO: 114 are useful in the treatment and/or detection of vascular disorders including vasculitis, cardiovascular disorders such as myocardial infarction, myocarditis, ischemia and stroke, as of the filling date. Until some actual and specific significance can be attributed to the protein identified in the specification as SEQ ID NO: 114 and antibodies against SEQ ID NO:114, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

No single effect of the disclosed Gene No:48 encoding SEQ ID NO: 114, is ascribed to the polypeptide and hence to the antibodies against those polypeptide. Note that while the specification produces the full-length protein recombinantly, no biological activity is established for the full length protein or any of the claimed fragments thereof. As such, further research would be required to identify or research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved would be required. Since the instant specification does not disclose a "real world" use for SEQ ID NO: 114 and the claimed antibodies against SEQ ID NO:114, then the claimed invention as disclosed does not meet the requirements of 35 U.S. C. § 101 as being useful.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 25-41, 44-67, 69-84, 87-110 and 112-117 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

A. Further, the polypeptide encoded by the cDNA contained in ATCC deposit Number 203081 recited in claims 13 (which depends from non-elected claim 11), 69, 87 and 95 are essential to the claimed invention. The reproduction of the polypeptide from the disclosed deposit No. 203081 is an extremely unpredictable event because it is known that bacteria contain multiple different clones with the same antibiotic resistant would lead to selective pressure favoring some clones over others and there is no guarantee that the cDNA encoding the polypeptide of SEQ ID NO: 114 is going to be selected over time. The vector, Uni-XAP XR comprising the cDNA encoding the polypeptide of SEQ ID NO: 114, disclosed in table 1, page 174, 5th row of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the vector, and it is not apparent if the vector is readily available to the public.

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the vector has been deposited under the Budapest Treaty and that the vector will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer*. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the vector described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the

depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

B. Besides the isolated polypeptide comprising SEQ ID NO: 114 and the amino acid 2-182, 32-182 of SEQ ID NO: 114 the specification fails to provide any guidance as to how to make an isolated antibody that binds specifically to a polypeptide comprising an amino acid sequence "at least 95% identical" to a) any "polypeptide fragment" of SEQ ID NO: 114 or encoded sequence included in ATCC Deposit No: 203081 in non-elected claim 11a, having a biological activity in non-elected claim 11b, c) a "polypeptide domain" of SEQ ID NO: 114, or the encoded sequence included in ATCC Deposit No: 203081 in non-elected claim 11c, d) a "polypeptide epitope" of SEQ ID NO: 114, or the encoded sequence included in ATCC Deposit No. 203801 in non elected claim 11d, a "secreted form" of SEQ ID NO: 114, or the encoded sequence included in ATCC Deposition: 203801 in non-elected claim 11e, f) a "variant" of SEQ ID NO: 114, in non-elected claim 11g, g) an "allelic variant" of SEQ ID NO: 114 in non elected claim 11h or h) a "species homologue" on the SEQ ID NO: 114 in non-elected claim 11i; or an isolated antibody or fragment thereof that specifically binds to a protein consisting of the full-length, the mature form, a portion,of the polypeptide of encoded by the cDNA contained in ATCC Deposit Number 203081 in claims 69, 87 and 95, The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant has not provided sufficient biochemical information (e.g. nucleic acid sequences, etc.) that distinctly identifies the variants, allelic variants and species homologue of SEQ ID NO: 114 other than those encompassed by set forth in SEQ ID NO:114. "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992). The specification fails to provide variants including allelic and species homologue of SEQ ID NO: 114. Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed protein in manner reasonably correlated with the scope of the claims broadly including any number of variants, allelic variants and species homologue of SEQ ID NO: 114. The scope of the claims must bear a reasonable correlation with the scope of enablement. The specification does not provide for sufficient enablement for variants including allelic and species homologue of SEQ ID NO: 114 other than those defined by SEQ ID NO: 114; which in turn, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Regarding the antibody that binds specifically to a polypeptide comprising an amino acid sequence at 95% identical to a polypeptide fragment, domain, epitope or secreted from of SEQ ID NO: 114.). Colman *et al* in Research in Immunology (145(1):33-36, 1994) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza *et al* in Journal of Protein Chemistry (11(5):433-444, 1992) teach that single amino acid substitutions

outside the antigenic site on a protein effect antibody binding. Further, Lederman *et al* in Molecular Immunology (28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Additionally, Li *et al* in PNAS (77:3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

The ATCC deposit No. 203081 contains multiple different clones. It is recognized in the prior art that the multiple insertions in the same strain are only limited by the availability of distinct selection markers. Given the lack of marker specific for SEQ ID NO: 114, thus the claimed antibody is not specific for SEQ ID NO: 114 but the antibody would be raised against (bind to) multiple different proteins encoded by the multiple different cDNA contained in ATCC Deposit No. 203081 (see table 1 for all the genes contained in the ATCC Deposit No. 203081). Further, the reproduction of the polypeptides from the disclosed deposit No. 203081 is an extremely unpredictable event because it is known that bacteria contain multiple different clones with the same antibiotic resistant would lead to selective pressure favoring some clones over others and there is no guarantee that the cDNA encoding the polypeptide of SEQ ID NO: 114 is going to be selected over time.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. Claims 13, 69-84 and 87-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an antibody or portion thereof that specifically binds to a protein of SEQ ID NO: 114, a protein consisting of amino acid residues 2-182, 32-182 of SEQ ID NO: 114 or a protein consisting of a portion of SEQ ID NO: 114, wherein said portion comprises at least 30/50 contiguous amino acids of SEQ ID NO: 114.

Applicant is not in possession of any isolated antibody that binds specifically to a polypeptide comprising an amino acid sequence "at least 95% identical" to a) any "polypeptide fragment" of SEQ ID NO: 114 or encoded sequence included in ATCC Deposit No: 203081 in non-elected claim 11a, having a biological activity in non-elected claim 11b, c) a "polypeptide domain" of SEQ ID NO: 114, or the encoded sequence included in ATCC Deposit No: 203081 in non-elected claim 11c, d) a "polypeptide epitope" of SEQ ID NO: 114, or the encoded sequence included in ATCC Deposit No. 203801 in non elected claim 11d, a "secreted form" of SEQ ID NO: 114, or the encoded sequence included in ATCC Deposition: 203801 in non-elected claim 11e, f) a "variant" of SEQ ID NO: 114, in non-elected claim 11g, g) an "allelic variant" of SEQ ID NO: 114 in non elected claim 11h or h) a "species homologue" on the SEQ ID NO: 114 in non-elected claim 11i; or an isolated antibody or fragment thereof that specifically binds to a

protein consisting of the full-length, the mature form, a portion, of the polypeptide of encoded by the cDNA contained in ATCC Deposit Number 203081 in claims 69, 87 and 95.

The ATCC deposit No. 203081 contains multiple different clones and it is unclear which protein, which the claimed antibodies bind to, is being referred to in the claims.

Applicant has disclosed only amino acid of SEQ ID NO: 114; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
June 24, 2004

CHRISTINA CHAN
RVISORY PATENT EXAMINER
NOLOGY CENTER 1600